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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,070	10/15/2003	Henrik Hansen	10177-232	8917
20583	7590	03/29/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			PADGETT, MARIANNE L	
			ART UNIT	PAPER NUMBER
			1762	
DATE MAILED: 03/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/687,070

Applicant(s)

HANSEN, HENRIK

Examiner

Marianne L. Padgett

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 15, 16, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 11, 14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/5/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. The thermal disclaimer of 11/5/04 has been approved, hence overcoming the obvious double patenting rejection of section 3 of the action of 5/6/04.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10, 12, 15-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (6,355,058 B1), in view of Escallon et al (4,749,125) and Cobbs, Jr. et al (4,550,957), as applied in section 5 of the 5/6/04 action.

Applicant's amendment has changed the intended use of the previous preambles in independent claims to a required substrate surface, however the primary reference, Pacetti et al is already directed to electrostatic spray coating (liquid or powder) particles with in a polymeric binder, onto all surfaces of a "stent", which is a medical device as claimed, which is implanted in "body tissue" hence meets the "adjusted to expose..." limitation. Therefore, the amendments make no significant difference in the claims with respect to the applied references. Applicant's statement on p. 7 of the 11/5/04 response, that "Pacetti does not disclose or suggest the presently claimed method of coating at least a portion of a medical device" is not agreed with, as the very title of the patent suggest medical devices substrates, unless applicant means that the primary reference is not a 102, which is clear from the 103 rejection. It is not necessary for the primary reference in a combination 103 rejection to be a 102. As stated in the 5/6/04 rejection, Pacetti does not teach particular electrostatic spray apparatus, or hence their particular apparatus or

procedural features. Nor is not necessary that the secondary references have all features of the claims, hence Escallon et al need not treat the generically claimed medical devices to have a relevant electrostatic spray process applicable to the teachings of Pacetti. Applicant's arguments that relies on al references teaching all feature are not convincing, and has not provided convincing arguments against the combination.

4. The Pui et al references cited by applicant (11/5/04 IDS) are noted as of interest for type of substrate treated (medical or body tissue) via an electrostatic spray technique, however the one that is prior art (869) charges the particles produces at the nozzle and does not appear to employ polymeric material in the sprayed solutions.

The patent to Noakes et al is cited as equivalent to Escallon et al (125), noting that it has electrostatic sprayed solution, where the charged is preferable provided via the body of the sources material (col.3), but while used to spray personal hygiene/car products, that may be considered types of medical devices, they do not appear to mention use of polymers in their solutions (§ bridge col. 5-6).

Zhong et al (6,676,987 B2) is cumulative to the above rejection or equivalent to Pacetti et al, as it also shows electrostatic sprayings of medical devices such as stents (abstract; figures; col. 1, lines 5-18<sup>+</sup>; summary), and the coating may included polymeric material with suspension of a medically related additive, where the delivery medium is formulated appropriately for the desired viability of additives (col. 3, lines 61-col. 4, line 63<sup>+</sup>). Droplets are formed and directed towards the substrate, however none of the discussion in Zhong et al (col. 5, line 38-col. 7) appears to indicate where the charge is placed on the coating material, i.e. in the bulk source or after droplet formation. In the source would appear appropriate, but is not disclosed.

Gilliard et al (6,811,805 B2  $\equiv$  2002/0182316 A1) teach various spray process for coating medical device including electrostatic, but are generic for the structure of such apparatus, therefore equivalent to Pacetti et al, with [0043-0048] discussing various compositions of polymeric liquid coating and useful solvents (alcohols).

Weber et al (2004/085168 A1) and Verlee et al (2004/0202773) are of interest for electrospraying medical devices, but are not prior art.

5. Claims 11, 13-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Applicant's arguments filed 11/5/04 and discussed above have been fully considered but they are not persuasive.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

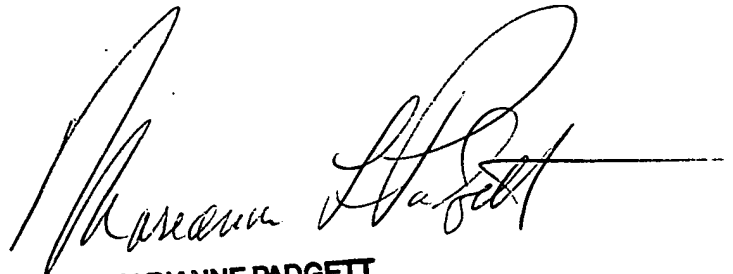
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to M L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on Monday-Friday about 8:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on (571) 272-1423. 5. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. L. Padgett/af  
January 31, 2005  
March 24, 2004



MARIANNE PADGETT  
PRIMARY EXAMINER